In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1835V

UNPUBLISHED

LOURDES OSORIO, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Roth Filed: July 9, 2021 Dismissal Decision; Influenza (Flu) Vaccine; Guillain-Barré Syndrome (GBS)

Bridget Candace McCullough, Muller Brazil, LLP, Dresher, PA, for Petitioner.
Julia Marter Collison, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT, CONCLUSIONS OF LAW AND DECISION DISMISSING CASE [1]

On November 29, 2018, Lourdes Osorio filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,[2] (the "Vaccine Act"). Petitioner alleges that she received an influenza ("flu") vaccine on December 5, 2015, and thereafter suffered from Guillain-Barré syndrome ("GBS"). Petition at 1.

Petitioner filed a Motion for a Ruling on the Record on June 19, 2020, arguing that she established a Table injury and is entitled to compensation. Motion for Ruling on the Record ("Pet. Mot.") ECF No. 30 at 5-7. Respondent filed a response on July 28, 2020.

[1] Although I have not formally designated this Decision for publication, I am required to post it on the United States Court of Federal Claims' website because it contains a reasoned explanation for the action in this case, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Respondent's Response to Petitioner's Motion for Ruling on the Record ("Resp. Res.") ECF No. 33. Petitioner did not file a reply. For the reasons discussed below, this claim is hereby **DISMISSED**.

I. Procedural History

Petitioner filed her petition on November 29, 2018, alleging she suffered from GBS caused by a flu vaccine administered on December 5, 2015. ECF No. 1. Petitioner received the flu vaccine in the United States but was initially diagnosed with GBS while in the Dominican Republic ("DR"). *Id.* at 1. Petitioner filed medical records with her petition, but not records from her time in the DR. *See* Pet. Ex. 1-5.

Between January 24, 2019 and May 29, 2019 Petitioner filed five Motions for Enlargement of Time within which to file medical records. Petitioner's counsel advised that this case was filed prior to collecting all relevant records because of the "pressing statute of limitations", and difficulty communicating with providers in the DR. ECF No. 8 at 1, ECF No. 9 filed February 26, 2019; ECF No. 12 filed March 28, 2019 (describing the efforts made to obtain records from the DR); ECF No. 15 filed April 29, 2019 (stating that providers in the DR have been unresponsive to requests due to an outstanding past due balance for services rendered); ECF No. 16 filed May 29, 2019.

On June 11, 2019, Petitioner filed a status report stating that she would not be receiving additional records and requested a status conference to discuss how best to proceed. ECF No. 17.

During the status conference, Petitioner's counsel recounted the efforts to obtain medical records from the DR. ECF No. 18, Scheduling Order filed June 19, 2019. At that time, Petitioner intended to travel to the DR before the fall of 2019 to secure the records. The parties also discussed issues with Petitioner's claim that the medical records were needed to resolve, which included the onset of Petitioner's GBS and an alternative cause for her GBS, namely a gastrointestinal illness. I informed Petitioner's counsel that this claim cannot prevail without records from the DR supporting her allegations.

Petitioner filed a status report and correspondence on July 18, 2019, which included assurances by Fruit Cruz Almonte,[3] an attorney retained by Petitioner in the DR, that the records would be delivered to Petitioner's counsel within four days. ECF No. 19.

Petitioner then filed a one-page record in Spanish on July 30, 2019. ECF No. 22. In a status report filed that same day, Petitioner's counsel conceded more records exist, portions of which can be found in other exhibits filed (*see* Pet. Ex. 2 at 1635). However,

[3] Mr. Almonte's name is spelled at least three different ways, including Fruit Cruz Alamonte (ECF No. 19 at 1), Fruto Cruz Almonte (Pet. Ex. 14 at 1), and Fruit Cruz Almonte (Pet. Ex. 14 at 1).

it was counsel's belief, based on representations of Mr. Almonte, that the one-page record was "the only kind of record that will be released." ECF No. 22.

On November 4, 2019, respondent filed a Rule 4(c) Report recommending against compensation. ECF No. 24. Respondent's position was based in part on the arguments that Petitioner had not met the six-month sequela requirement; had not established a Table injury because onset was outside the 42-day period set forth in the Vaccine Injury Table; that there is a more likely alternative diagnosis for her injury, namely a diarrheal illness; and that Petitioner had not established her injury was caused-in-fact by the vaccination. *Id.* at 11-16. Respondent also noted that certain records may still be outstanding. *Id.* at 10.

Petitioner filed a status report on February 3, 2020, advising her claim cannot be resolved and she was unable to meet her burden without additional records from the DR. ECF No. 26. Petitioner requested 45 days to inform the Court how she intended to proceed.

During a status conference on April 21, 2020, Petitioner's counsel advised that she was unable to obtain additional records from the DR, acknowledging that the current records filed were insufficient to support entitlement. However, petitioner was unwilling to dismiss her claim but was amenable to a ruling on the record. ECF No. 29.

Petitioner filed her Motion for a Ruling on the Record on June 19, 2020, arguing she had established a Table claim and was thus entitled to compensation. Pet. Mot. at 5-7. Respondent filed a response on July 28, 2020. Resp. Res. Petitioner did not file a reply.

II. Factual Background

Petitioner received a flu vaccine on December 5, 2015. Pet. Ex. 1. At that time, Petitioner was 58 years old and suffered from poorly controlled Type 2 diabetes. Pet. Ex. 13 at 4; Pet. Ex. 2 at 157; Pet. Ex. 4.

Between December 18, 2015 and January 6, 2016, Petitioner saw her primary care provider ("PCP") four times for reasons related to her diabetes. Pet. Ex. 4 at 70-80. More specifically, she presented on December 18, 2015 for follow up of her diabetes with an inability to get her blood sugar levels under 400. *Id.* at 78. She presented on December 23, 2015 for re-evaluation, and despite increase in insulin, her fingerstick results continued to be at 400. She complained of being very thirsty and urinating a lot. *Id.* at 75. At her December 30, 2015 visit she reported taking her medication, eating healthy and walking every day. *Id.* at 73. Petitioner presented again on January 6, 2016 as a walk-in due to elevated blood sugar level that morning. Her examination was normal, with no fever, chest pain, shortness of breath or dizziness. She was to follow up in three

months. *Id.* at 69-72. There were no reports of any symptoms associated with GBS or reports of tingling or weakness in her extremities at any of these visits. *Id.*

In January of 2016, Petitioner traveled to the DR. Pet. Ex. 12 at 12. On or about February 5, 2016, while in the DR, Petitioner presented to a local hospital reporting a two-day history of diarrhea. Pet. Ex. 2 at 1656-48; Pet. Ex. 15. Three days later, on or about February 8, 2016, Petitioner was admitted to Policlinico Union with complaints of generalized weakness and difficulty breathing. Following a lumbar puncture and cranial tomography, Petitioner was diagnosed with GBS. Pet. Ex. 2 at 1653. Between February 8, 2016 and February 19, 2016, Petitioner was in the intensive care unit at Policlinico Union. Pet. Ex. 2 at 1656. Her diagnoses included GBS and acute diarrheal disease. *Id.*

Petitioner returned to the United States on February 19, 2016, and was admitted to the ICU at Wellstar Cobb Hospital in Austell, GA with a history of diarrheal illness one week prior to hospitalization on February 8, 2016. Pet. Ex. 2 at 147-151. On February 20, 2016, Dr. Huff treated Petitioner and noted that her condition was "[l]ikely Guillain Barre syndrome - ascending paralysis post infectious diarrhea." *Id.* at 147. Dr. Huff also reported that Petitioner "was in the DR with her family" and "started having a diarrheal illness." She seemed to improve but returned to the hospital on February 8 with weakness and tingling in her legs. *Id.* at 148. Petitioner was also evaluated by a neurologist on February 20, 2016, who noted that Petitioner had experienced a diarrheal illness and "developed ascending numbness and weakness" thereafter. *Id.* at 169.

On February 24, 2016, Petitioner had a consult with a rehabilitation specialist. Pet. Ex. 2 at 156-57. The specialist documented Petitioner's history, including her developing a diarrheal illness while vacationing with her family in the DR. *Id.* at 156-57.

Petitioner was discharged from the hospital on March 4, 2016 and transferred to inpatient rehabilitation. Pet. Ex. 2 at 151-56. At the time of her transfer the medical record documented that Petitioner's GBS may have been caused by a mosquito bite-related viral infection. *Id.* at 152.

At the time of admission to the inpatient rehabilitation facility, her condition was described as progressive weakness and numbness in her extremities after a diarrheal illness. Petitioner remained in the inpatient rehabilitation facility for two weeks. Pet. Ex. 2 at 1025. She was discharged on March 18, 2016. Pet. Ex. 3 at 16-24. Petitioner had near-full strength with good knee reflexes, normal speech, but reduced reflexes below the knee at discharge. Pet. Ex. 2 at 705.

Petitioner next sought care five months later on August 4, 2016, when she presented to her PCP and "said she got GBS at the end of January possible 2/2 influenza vaccine that she got on 12/15/15…." Pet Ex. 4 at 67.[4] Petitioner again saw her PCP on November 2, 2016, who noted a history of GBS that had an "unclear cause possible influenza vaccine?" *Id.* at 59-63.

On November 2, 2016, Petitioner underwent an EMG nerve conduction study. Pet. Ex. 4 at 446. The study revealed evidence of mild, mixed, primarily motor polyneuropathy involving the lower extremities. *Id.*

On November 29, 2016, Petitioner consulted with an endocrinologist who documented a twenty-year history of Type 2 diabetes for which she did not follow a proper diet or exercise. Pet. Ex. 10 at 11-12. She complained of numbness and tingling, but a neurological examination showed her strength and reflexes were within normal limits. *Id.*

Petitioner complained of balance and strength issues several times in late November and December of 2016. Pet. Ex. 4 at 91; Pet. Ex. 8 at 6-8. On December 28, 2016, Petitioner presented for a physical therapy consult and reported multiple falls. Pet. Ex. 8 at 6-8. Examination on that date revealed Petitioner's muscle strength as slightly reduced, sensation in her hands and feet were decreased, and her lower extremity reflexes were also reduced. Further, Petitioner exhibited mobility problems, such as slow and unsteady walking. *Id.*

Petitioner presented for several medical appointments between January and August of 2017, which included her PCP, a neurologist and an orthopedist due to a fall and leg fracture. Pet. Ex. 4 at 54-55; Pet. Ex. 5 at 34-36; Pet. Ex. 7 at 12-13; Pet. Ex. 8 at 52-53.

On January 18, 2018, over three years after her flu vaccination, Petitioner consulted with a speech pathologist complaining of persistent speech and swallowing difficulties. Pet. Ex. 12 at 16-17. During that visit Petitioner, for the first time, reported that the tingling in her extremities began as early as December of 2015. *Id.* at 16.

On February 8, 2018, Petitioner consulted with Dr. Pleninger, a neurologist. Pet. Ex. 12 at 13-15. At this examination, Petitioner reported that she received a flu vaccine in November, then traveled to the DR in January where she was diagnosed with GBS.[5] She

[4] Petitioner's flu vaccine was administered on December 5, 2015. Pet. Ex. 1.
[5] Petitioner actually received a flu vaccine on December 5, 2015 and was diagnosed with GBS following a February 8, 2016 admission to a hospital in the DR following a diarrheal illness.

reported that tingling in her hands began in December of 2015. *Dr. Pleninger* attributed her complaints to her diabetes and uncontrolled sugars. *Id.* at 13.

III. Legal Standard

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[6] a petitioner must establish that she suffered an injury meeting the Table criteria (*i.e.* a Table injury), in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. If a petitioner establishes a Table injury the burden shifts to respondent to establish a more likely alternative cause. Section 13(a)(1)(A), 11(c)(1)(C)(i), 14(a). If a petitioner cannot establish a Table injury, he or she may pursue causation-in-fact under the legal standard set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the

[6] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* § 11(c)(1)(A)(B)(D)(E).

time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, GBS is compensable if it manifests within 3-42 days (not less than three days and not more than 42 days) of the administration of an influenza vaccination. 42 C.F.R. § 100.3(a)(XIV)(D). (Further criteria for establishing a GBS Table Injury case be found under the accompanying qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(15)).

Cases alleging a Table GBS injury have often been dismissed for failure to establish proper onset. *See, e.g.*, *Randolph v. Sec'y of Health & Human Servs.*, No. 18-1231V, 2020 WL 542735, at *8 (Fed. Cl. Spec. Mstr. Jan. 2, 2020) (finding GBS onset at the earliest occurred 76 days post-vaccination, "well outside the 3-42-day window set by the Table for a flu-GBS claim"); *Upton v. Sec'y of Health & Human Servs.*, No. 18-1783V, 2020 WL 6146058, at *2-3 (Fed. Cl. Spec. Mstr. Sept. 24, 2020) (finding the petitioner did not establish the onset of his GBS within the 3-42 day time frame prescribed and thus did not establish a Table Injury).

IV. Analysis

Petitioner asserts that she is entitled to compensation because she has established a Table injury. Pet. Mot. at 5. Specifically, Petitioner submits that the onset of her GBS was within the prescribed timeframe (*i.e.* within 30 days of her vaccination), and that her GBS progressed and occurred prior to the traveler's diarrhea she experienced in February of 2016. *Id.* at 5-6. Petitioner also asserts that she meets the six-month sequela requirement. *Id.* at 6-7. Respondent argues that Petitioner has not met the table requirements because the onset of her GBS was 65 days after her vaccination, well outside the 42-day period set forth in the Table. Further, Respondent asserts that he has established a more likely alternative cause of her GBS, namely a gastrointestinal illness, that Petitioner has not established causation-in-fact, and that Petitioner has not met the six-month sequela requirement.

For the reasons set forth below, I find that the onset of Petitioner's GBS was 65 days after her vaccination and following a gastrointestinal illness. Further, Petitioner has not established, by preponderant evidence, either a Table injury or causation-in-fact.

a. Petitioner Has Not Established a Table Claim

The following factual findings are made after a complete and thorough review of the record, including all medical records, affidavits, and all other additional evidence

and filings from the parties.[7]

Petitioner alleges she suffered a Table GBS injury following a flu vaccine administered on December 5, 2015. Pet. Mot. at 5-6. However, contemporaneous medical records preponderantly establish that the initial symptoms of Petitioner's GBS did not occur until February 8, 2016, 65 days after her vaccination, when petitioner presented to the hospital in the DR with generalized weakness and difficulty following a gastrointestinal illness for a week. Pet. Ex. 5 at 153. Further, Petitioner's contemporaneous medical records consistently document that her symptoms did not begin until February of 2016 after a diarrhea infection. *See*, *e.g.*, Pet. Ex. 2 at 147 (record from February 19, 2016 stating Petitioner's condition included "ascending paralysis post infectious diarrhea"); *Id.* at 169 (record from February 20, 2016 noting Petitioner experienced a diarrheal illness and developed numbness and weakness thereafter); *Id.* at 1025 (record from March 4, 2016 stating that Petitioner's progressive weakness and numbness occurred after a diarrheal illness). Petitioner's contemporaneous medical records not only support onset outside of the 42-day limit for a viable Table flu-GBS claim, but also outside the *longest time* accepted for a similar non-Table claim in the Program. *See, e.g.*, *Barone v. Sec'y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (finding eight weeks (56 days) is the longest reasonable timeframe for a flu vaccine/GBS injury).

In contrast to the above, Petitioner references medical records documenting onset of her symptoms as prior to her February 8, 2016 hospitalization. Pet. Mot. at 6. However, the earliest of these records referenced was dated August of 2016, significantly after Petitioner's hospitalization, contains inaccurate dates and little context (temporal or otherwise) regarding onset of her injury. *See*, *e.g.*, Pet. Ex. 4 at 67 (record from August 4, 2016 documenting "Pt said got GBS at the end of January…."). Further, the records show that Petitioner began reporting the onset of her symptoms as December of 2015 over two years later and three years after the alleged vaccine. Pet. Ex. 12 at 13-15 (consultation with Dr. Pleninger on February 8, 2018 reporting her symptoms began in December of 2015). Moreover, multiple records contemporaneous with the events are silent as to the existence of any GBS symptoms. For example, Petitioner saw her primary care provider numerous times between December 18, 2015 and January 6, 2016 for follow up care for her diabetes, her inability to control her sugar levels and reporting compliance with her medication, diet and walking every day. Pet. Ex. 4 at 78, *id.* at 75, *id.* at 73, *id.* at 69-72. At no time did she mention any complaints of tingling or weakness

[7] Though every document is not specifically referenced in this ruling, the complete record was reviewed and considered. *See Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision.").

in her extremities at any of these visits, the last visit being January 6, 2016 just prior to her leaving for the DR.

When the record is read in its entirety, the evidence of a purportedly earlier onset is outweighed by the contemporaneous evidence. Further, it is legally proper to give contemporaneous records from the time Petitioner sought treatment for her GBS symptoms following a diarrheal illness (after February 8, 2016) greater weight. "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras*, 993 F.2d at 1528.

Moreover, even if Petitioner's assertions about an earlier onset were given more weight, they would describe a GBS course inconsistent with what is known about the illness. GBS is, in the vast majority of cases, an acute and monophasic condition. It is not known to present with a slow, smoldering malaise that thereafter remains subacute for weeks or months. *Chinea v. Sec'y of Health & Human Servs.*, No. 15-095V, 2019 WL 1873322, at *31, 33 (Fed. Cl. Mar. 15, 2019), *review denied*, 144 Fed. Cl. 378 (2019) (finding that the onset of the petitioner's GBS occurred eleven to twelve weeks after her vaccination, which was beyond the six- to eight-week medically appropriate timeframe for the occurrence of vaccine-induced GBS). It is not preponderantly likely that Petitioner would have experienced GBS onset in the form she described in December of 2015, only to manifest acutely on February 8, 2016.

There is a preponderance of evidence that the onset of Petitioner's GBS occurred 65 days after her flu vaccination. This is well outside the 42-day window set forth in the Table, and therefore Petitioner has not met the criteria needed to establish a Table claim.[8]

b. Petitioner Has Not Established a Causation-In-Fact Claim

To proceed on a theory of causation-in-fact, a petitioner must show by a preponderance of the evidence that "a vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury."

[8] Respondent also argues that he has established, by preponderant evidence, that the injury was caused by factors unrelated to the vaccine. Resp. Res. at 7. Namely, that Petitioner's gastrointestinal illness was the cause of her GBS. *Id.* Because I have determined that Petitioner has not established a Table injury, it is unnecessary to address Respondent's argument.

Althen, 418 F.3d at 1278. Petitioner has not claimed her GBS was caused-in-fact by the flu vaccine. Even if Petitioner did allege causation-in-fact, her claim would not succeed.

Petitioner has not identified a scientific theory by which a flu vaccine can cause GBS in excess of eight weeks post-vaccination or offered evidence that it did so in this case. Therefore, Petitioner has not met the first prong of the *Althen* test.

With regard to the second prong, Petitioner has produced no evidence showing a logical sequence of cause and effect showing that the vaccine was the reason for the injury. Further, several of Petitioner's treating physicians contemporaneous to the events associated her GBS with a gastrointestinal infection. *See, e.g.*, Pet. Ex. 2 at 148 (Dr. Huff's impression was that petitioner was likely suffering from "GBS, ascending paralysis post infectious diarrhea."); *id.* at 152 (noting that Petitioner's GBS may have been caused by a mosquito bite-related viral infection).

In determining whether a vaccine "did cause" an injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1367 (Fed. Cir. 2009); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Further, special masters have denied entitlement where a petitioner suffered a well-documented gastrointestinal illness closer in time to her GBS diagnosis than her flu vaccine. *See, e.g.*, *Angdahl–Wangler v. Sec'y of Health & Human Servs.*, No. 16-1222V, 2016 WL 7423077 (November 28, 2016) (granting a motion to dismiss where GBS occurred nine and a half weeks after a flu vaccine but only one week after a diarrheal illness); *Brock v. Sec'y of Health & Human Servs.*, No. 12-756V, 2014 WL 2979425 (June 12, 2014) (denying entitlement where GBS occurred one month post flu vaccination, but in the setting of persistent intervening diarrheal illness caused by unconfirmed bacterial infection); *Aguayo v. Sec'y of Health & Human Servs.*, No. 12- 563V, 2013 WL 441013 (January 15, 2013) (denying entitlement where GBS occurred over three months after seasonal flu vaccine, over two months after H1 N1 flu vaccine, but within one week of a cold and diarrhea); *Pratt v. Sec'y of Health & Human Servs.*, No. 12-917V, 2013 WL 6626822 (November 21, 2013) (petitioner chose not to submit an expert report, and was denied entitlement after asserting GBS two-months post flu vaccination in the setting of prolonged intervening febrile & diarrheal illness).

Further, petitioner has not presented reliable scientific or medical evidence establishing that the time between her flu vaccination and the onset of symptoms would be considered "medically acceptable to infer causation-in-fact." *See de Bazan v. Sec'y of Health & Human Servs. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Moreover, as noted above, the *longest time* accepted for onset of GBS in a non-

Table claim is 56 days after vaccination. *See, e.g.*, *Barone,* 2014 WL 6834557, at *13 (finding eight weeks (56 days) is the longest reasonable timeframe for a flu vaccine/GBS injury). Petitioner's onset of 65 days is outside even this period.

V. Conclusion

The evidentiary record does not support Petitioner's contention that the flu vaccine she received in December of 2015 caused her GBS in the timeframe proffered, does not support the allegation that she suffered a Table Claim, and would not support allegations that her GBS was caused-in-fact by the flu vaccine. Because Petitioner has failed to establish any of the foregoing, whether she satisfied the six-month severity requirement is moot.

Petitioner has not established entitlement to a damages award, and therefore I must **DISMISS** her claim in its entirety. **The clerk shall enter judgment accordingly.**[9]

IT IS SO ORDERED.

s/Mindy Michaels Roth
Mindy Michaels Roth
Special Master

[9] If Petitioner wishes to bring a civil action, he must file a notice of election rejecting the judgment pursuant to § 21(a) "not later than 90 days after the date of the court's final judgment."